Food and Drug Administration
Center for Food Safety and Applied Nutrition
Office of Special Nutritionals

ARMS#

13096

0 - FRONT

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
FOOD AND DRUG ADMINISTRATION
COMPLAINT/INJURY REPORT

1. COMPLAINT NUMBER: SAN-2900

2. DATE OF COMPLAINT (MM/DD/YY): 10/29/98

3. FORM OF COMPLAINT
[^] (1) TELEPHONE [^] (3)VISIT
[X] (2)LETTER/FAX

4. SOURCE OF COMPLAINT
[^] (1) CONSUMER
[^] (2) GOVERNMENT
[^] L [^] S [^] F
[^] (3) TRADE SOURCE
[X] (4) OTHER (Indicate in Remarks)

5. COMPLAINANT IDENTIFICATION
[redacted]

b. AREA CODE AND TELEPHONE
HOME (^)
WORK [redacted]

6. COMPLAINT OR INJURY

a. DESCRIPTION OF COMPLAINT/INJURY
This complaint was generated for an CFSAN Adverse Reaction Monitoring Request. Consumer used product and it is believed the product died as a result.

[redacted] Deceased 37 y/o female
Information gathered and completed by CSO Arezzo.

b. DOES COMPLAINT EXPECT ADDITIONAL FDA CONTACT? [X] NO [^] YES (Explain In Remarks)

7. INJURY OR ILLNESS RESULTED
[^] (1) NO
[X] (2) YES
(If "YES" complete items a through d)

a. EIB (HFC-161) NOTIFIED
[^] (1) NO
[^] (2) YES
DATE
CFSAN alerted

b. TYPE SYMPTOMS
[^] (1) VOMITING
[^] (2) NAUSEA
[^] (3) DIARRHEA
[^] (4) FEVER
[^] (5) SKIN/EYE IRR.
[^] (6) HEADACHE
[X] (7) OTHER

ONSET (HRS)

c. ATTENDING HEALTH PROFESSIONAL
[^] (1) NO
[X] (2) YES (If "yes" give name address, and phone no.)
Please refer to report completed via CSO Arrezzo

d. HOSPITALIZATION REQUIRED
[^] (1) NO
[X] (2) YES (If "yes" give name address, and phone no. and dates)
See 7c.

8. PRODUCT AND LABELING

a. BRAND NAME: Metabolite 356

b. PRODUCT NAME: herbal supplement

c. SIZE AND PACKAGE TYPE: n/a

d. NAME AND LOCATION OF STORE WHERE PURCHASED: n/a

e. PACKAGE CODE/SERIAL NUMBER/ETC.: n/a
EXP/USE BY DATE: ^

f. DATE PURCHASE: n/a

g. PRODUCT USED (If "yes enter date): n/a
[^] (1) NO [^] (2) YES

1h. AMT REMAINING: n/a

9. MFGR/DSTR OF PRODUCT

a. HOME DISTRICT: A

b. C.F.NO.: NO CFN

c. NAME AND ADDRESS OF FIRM (Include Zip Code)
Metabolite International
5070 Santa Fe Street
San Diego, CA 92109

d. IMPORT PRODUCT
[X] (1) NO
[^] (2) YES

10. EVALUATION AND DISPOSITION

a. PROBLEM (1) CODE: DT
KEYWORD (2) DESCRIPTION: death

b. EVALUATION
[^] (1) NOT AN FDA OBLIGATION
[^] (2) OBLIGATION, NO VIOLATION
[X] (3) FDA ACTION INDICATED
[^] (4) INSUFFICIENT INFORMATION UNABLE TO EVALUATE

c. DISPOSITION
[X] (1) IMMEDIATE FOLLOW-UP
[^] (2) F/U NEXT EI
[^] 3) CLOSED WITHOUT FURTHER INVESTIGATION
[^] (4) REFERRED TO OTHER FEDERAL AGENCY (Closes file)
[^] (5) REFERRED TO STATE/ LOCAL AGENCY
[^] (6) REFERRED TO OTHER FDA ^ DISTRICT
[^] (7) REFERRED TO OCI

11. PRODUCT CODE: 54FC-09

12. INFORMATION
[^] HFM - 660
[^] HFD - 730
[^] HFV - 210

COPIES TO:
[^] HFZ - 343
[^] HFC - 161
[^] HFS - 636
[^] HFC - 151

13. REMARKS
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OPTIONAL FORM 99 (7-90)

FAX TRANSMITTAL

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To B. Wallace
Dept./Agency CFSAN
Fax # (202) 260-0133

From [redacted]
Ph
Fax

14. NAME AND TITLE
Frank A. Arezzo, CSO

16. DATE
10/30/98

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GOLD

FORM FDA 2516 (4/85)
NSN 7540-01-317-7388 5099-101 GENERAL SERVICES ADMINISTRATION